DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

93156d

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

March 18, 2002

Ref: 2002-DAL-WL-12

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Mr. Richard L. Hayes, Owner
Richard Hayes Cattle Company
Route 4, Box 186B
Hereford, Texas 79045

Dear Mr. Hayes:

An inspection conducted by our investigator at your cattle buyer/dealer operation located at Hereford, Texas, on February 11-12, 2002, confirmed that you offered animals for slaughter as food in violation of Sections 402(a)(2)(C)(ii), and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about June 29, 2001, you delivered and offered for slaughter as human food, a steer identified with ear tag 667490 to [redacted]. USDA analysis of tissue samples collected from that animal identified the presence of 9.90 ppm of tilmicosin in the liver, and 13.70 ppm tilmicosin in the muscle tissue. A tolerance of 1.2 ppm has been established for residues of tilmicosin in the edible tissues of cattle [Title 21, Code of Federal Regulations (CFR) Part 556.735]. The presence of this drug in edible tissue from this animal causes the food to be adulterated.

On or about June 29, 2001, you delivered and offered for slaughter as human food, a steer identified with ear tag 1076 to [redacted]. USDA analysis of tissue samples collected from that animal identified the presence of 0.36 ppm penicillin in the kidney, and 0.07 ppm penicillin in the liver tissue. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of cattle (21 CFR 556.510). The presence of this drug in edible tissue from this animal causes the food to be adulterated.

On or about October 5, 2001, you delivered and offered for slaughter as human food, a steer identified with ear tag COR632 to [redacted]. USDA analysis of tissue samples collected from that animal identified the presence of 0.34 ppm sulfadimethoxine in the muscle tissues. A tolerance of 0.1 ppm has been established for residues of sulfadimethoxine in the edible tissues of cattle (21 CFR 556.640). The presence of this drug in edible tissue from this animal causes the food to be adulterated.

On or about October 26, 2001, you delivered and offered for slaughter as human food, a steer identified with back tag 1203 and ear tag 9705 to [redacted]. USDA analysis of tissue samples collected from that animal identified the presence of 2.90 ppm of sulfadimethoxine in the muscle and 2.96 ppm in the liver tissue. A tolerance of 0.1 ppm has been established for residues of sulfadimethoxine in the edible tissues of cattle (21 CFR 556.640). The presence of this drug in edible tissue from this animal causes the food to be adulterated.

On or about November 6, 2001, you delivered and offered for slaughter as human food, a steer identified with back tag 3811 to [redacted]. USDA analysis identified the presence of 0.07 ppm penicillin in the kidney. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of cattle (21 CFR 556.510). The presence of this drug in edible tissue from this animal causes the food to be adulterated.

On or about November 13, 2001, you delivered and offered for slaughter as human food, a steer identified with ear tag 227 to [redacted]. USDA analysis of tissue samples collected from that animal identified the presence of 63.78 ppm gentamicin sulfate in the kidney, and 12.97 gentamicin sulfate in the liver tissue. No tolerance has been established for residues of gentamicin sulfate in the edible tissues of cattle (21 CFR 556.300). The presence of this drug in edible tissue from this animal causes the food to be adulterated.

Prior to the most recent inspection of February 11-12, 2002, you had been inspected by a representative of the Texas Department of Health on two previous occasions, January 24 and June 8, 2000. Those inspections revealed that you have no system in place to determine whether an animal you purchase and subsequently offer for slaughter as human food, has been medicated, and whether it should be withheld from slaughter in order to allow for potentially harmful drug residues to be depleted.

During the February 11-12, 2002, inspection, our investigator found essentially the same objectionable conditions observed by the Texas Department of Health. Our investigator also found that you hold animals under conditions so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack a system to

identify and quarantine treated animals you purchase from cattle sellers. Also, you lack a system for assuring that animals, medicated prior to your purchase have been withdrawn from medication for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated within the meaning 402(a)(4) of the Act.

The above is not intended to be an all-inclusive list of violations. As a buyer/dealer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law. As a dealer of animals, you are frequently the individual who introduces or offers for introduction into interstate commerce, the adulterated animal. As such, you share the responsibility for violating the Federal Food, Drug and Cosmetic Act. To avoid future illegal residue violations you should take precautions such as:

1. implementing a system to identify the animals you purchase with records to establish traceability to the source of the animal;

2. implementing a system to determine from the source of the animal whether the animal has been medicated and with what drug(s); and

3. if the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissue. If you do not want to hold the medicated animal then it should not be offered for human food, and it should be clearly identified and sold as a medicated animal.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that you caused the adulteration of an animal that was offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the

corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Attention: Reynaldo R. Rodriguez, Jr., Director, Compliance Branch, at the above letterhead address.

Sincerely,

Michael A. Chappell
Dallas District Director

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